The Efficacy of PI-RADS 5 Scoring in Predicting Presence of Clinically Significant Prostate Cancer on MRI-Fusion Biopsy

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Introduction

The Prostate Imaging Reporting and Data System (PI-RADS) is a structured reporting schema that helps determine the risk of clinically significant (CS) cancer on prostate multiparametric magnetic resonance imaging (mpMRI). PI-RADS 5 lesions are at the highest risk for CS cancer. However, a significant proportion of PI-RADS 5 lesions do not demonstrate CS cancer on the MRI-US fusion biopsy (FBx). In this study, we look to identify the common reasons behind the findings of benign or non-CS cancer on FBx of PI-RADS 5 lesions.

Methods

Study Population

- Retrospectively reviewed 665 patients
- Patients underwent MRI-US fusion biopsy at the University of Cincinnati Medical Center, from January 2014 to March 2020
- 176 had a PI-RADS 5 lesion and were further analyzed

Prostate Biopsy

- Prostate biopsies were performed as a single session, with Artemis machine-registration device
- Biopsies performed after patients underwent MRI
  - MRI then fused with live ultrasound to guide the biopsy
  - Patients underwent subsequent standard template biopsies as well

Study Data

- Demographic, clinical, and pathological data all recorded
- Clinically significant cancer defined as Gleason score of 7 or greater
- Patients with a PI-RADS 5 lesion and no finding of clinically significant cancer on MRI-US fusion biopsy were further assessed
- Patients reviewed by radiologist to confirm PI-RADS score of 5, then assessed for concurrent prostatic pathology

Statistical Analysis

- Analysis completed using computer software R 3.62 (R Core Team, 2017)
- Multivariate logistic regression was prepared to identify any confounding clinical or demographic variables
- Statistical significance was defined as a two-sided *p*-value < 0.05

Results

Patient Findings

665 total patients included in this study

- 176 had at least one PI-RADS 5 lesion
- Clinically significant cancer found in 135 (76.7%) patients
  - Aligns with literature on the accuracy of PI-RADS 5

41 PI-RADS 5 patients with no clinically significant cancer found on biopsy

- 34 (82.9%) patients had a correct PI-RADS 5 score
- 7 patients had MRI misreads
- 8 patients had a FBx registration error
  - MRI incorrectly depicted area of cancer
  - Clinically significant cancer found on template biopsy
- 26 patients had no clinically significant cancer finding on biopsy
  - This represented 14.7% of the total PI-RADS 5 population

Patient Demographics

- Patient population was divided into those with a PI-RADS 5 lesion and those without a PI-RADS 5 lesion
- The median age for our PI-RADS 5 and non-PI-RADS groups were 66 and 64, respectively
- The median PSA for our PI-RADS 5 and non-PI-RADS groups were 8.55 and 6.27 ng/mL, respectively

Logistic regression analysis demonstrated young age ($p = 0.01$), low total PSA ($p = 0.001$), and high prostate volume ($p = 0.001$) to be significant predictors of false PI-RADS 5 scores.

Total Patients Undergoing FBx	**665**
Total Patients with PI-RADS 5 Lesion	**176**
PI-RADS 5 Patients with Clinically Significant Cancer	**135**
PI-RADS 5 Patients without Clinically Significant Cancer	**41**

Table 1: Patients in database were filtered to determine patients with PI-RADS 5 lesion and no clinically significant cancer on biopsy.

Total Pts	41
Total MRI Misread	7 (17.1%)
Total Correct PIRADS 5	34 (82.9%)
Total FBx Registration Errors (n = 34)	8 (23.5%)
Total False Positives (n = 34)	26 (76.5%)

Table 2. Patients were reviewed to determine accuracy of PI-RADS 5 score.

Causes for Benign or Non-CS Findings on FBx (n = 26)	
True Gleason 6	12 (46.2%)
Chronic Inflammation/Prostatitis	6 (23.1%)
Benign Biopsy	6 (23.1%)
Acute Inflammation/Prostatitis	4 (15.4%)
Atrophy	4 (15.4%)
Therapy Related Changes	1 (3.8%)
Atypical Small Acinar Proliferation/Atypical Glands	0 (0%)
Prostatic Intraepithelial Neoplasia	0 (0%)

Table 3. Patients with true PI-RADS 5 lesion but no CS cancer on biopsy. All findings were in location of target biopsy. Some patients demonstrated multiple findings.

Conclusions

While PI-RADS scoring allows for better understanding of suspicious prostate lesions, it remains an imperfect system. Our study showed that only 76.7% of our PI-RADS 5 patient population had clinically significant prostate cancer. Unfortunately, the parameters to predict false positives are unknown. However, our work demonstrated potential pathology that may lead to this false positive finding. Further research is required to define these parameters.